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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,553	03/10/2004	William R. Moyle	1092/US PCT	4558

38070 7590 04/06/2007
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EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1647

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/797,553

Applicant(s)

MOYLE ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 9-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-8, in the reply filed on 1/16/07 is acknowledged.

Claims 9-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/16/07.

Specification

The disclosure is objected to because of the following informalities: Pages 25-26 appear to be missing some text. The bottom of page 25 is blank and the top of page 26 appears to start mid-sentence.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specifically exemplified glycoprotein hormone proteins having a tail portion and a knob, does not reasonably provide enablement for all proteins encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification discloses and exemplifies particular embodiments of proteins meeting the limitations of the claims with respect to tail and knob features. They are all modified glycoprotein hormones and have been used to elucidate the three-dimensional binding contact points of hCG to its receptor. However, the claims are not directed to methods but rather products. The products encompassed are not limited to any particular kind of protein. The specification does not disclose or provide guidance on how to make or use other proteins within scope of the claims. For example, the claims include substituting a cysteine in a protein such as an antibody. The specification provides no guidance on where to substitute the cysteine in the protein portion or what to consider the knob cysteine (the claims embrace any naturally occurring sequence containing a cysteine or mutated to contain a cysteine as forming a knob). The specification does not provide guidance such that one of ordinary skill in the art would be readily able to determine if the knob cysteine is located on the surface of the protein. (See claim 6). The specification does not provide guidance on producing other multimers within the scope of the claims. Furthermore, even if one of ordinary skill in the art produced an antibody or other monomer or multimer within the scope of the claims, the specification does not make clear how to use this composition. Arbitrary insertion of cysteines or arbitrary mutation of amino acids in a protein to cysteine would have been expected to have been deleterious to folding and thus to any biological activity.

The specification lacks and examples commensurate in scope to the breadth of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to a composition; however, there is a single protein component having a tail containing a knob. The claim is confusing because the term “composition” usually implies multiple components.

Claim 1 recites “desired location to be tagged.” The specification does not provide any criteria to determine what is or is not a desired location. It cannot be determined what the metes and bounds of the claim are. In the absence of more, the examiner considers all amino acid positions desired locations to be tagged.

Claims 4-5 are confusing in reciting that the knob comprises a protein or polypeptide. The specification does not appear to make a distinction between a protein or polypeptide and it is unclear how the claims differ in scope. In addition, the only recited limitations concerning a knob in claim 1 clearly indicates that the knob contains amino acids (i.e. is a protein or polypeptide). It is not clear how claims 4-5 further limit claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Moyle (WO 99/53065).

Moyle et al. discloses the β subunit of hCG (a protein portion) where a cysteine is substituted for a tyrosine. The β subunit of hCG leader sequence and part of the Jun protein is fused to the N-terminus of the β subunit of hCG meeting the limitation of a tail. Within this protein sequence is a cysteine meeting the limitation of a knob. In addition, this monomer was produced in combination with a modified α subunit of hCG. The α subunit of hCG can also be considered a tail having a knob as cysteines are present in the α subunit of hCG. Dimers were formed meeting the limitation of multimers (see claim 8). Inclusion of cleavage sites in the Jun region are disclosed. See at least abstract, claims, page 11, Examples 3 and 4 and Figures 12-13. With respect to claim 3, the specification does not particularly define what is required by an epitope tag. The knob sequences are of sufficient length to contain an epitope, absent evidence to the contrary. With respect to claim 6, the reference does not specify if the knob cysteine is on the surface of the protein; however and absent evidence to the contrary, it would appear to be on the surface (rather than buried and inaccessible) as it is capable of dimerizing.

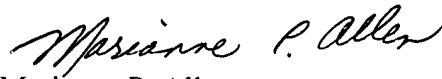
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Marianne P. Allen
Primary Examiner
Art Unit 1647

3/28/07

mpa